UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

In Re: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION

MDL NO. 2740

SECTION "N" (5)

THIS DOCUMENT RELATES TO ALL CASES

MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' MASTER LONG FORM COMPLAINT

I. INTRODUCTION

Plaintiffs in MDL 2740 are individuals who allege that Defendants' cancer drugs Taxotere, Docefrez, Docetaxel Injection and Docetaxel Injection Concentrate (hereinafter, collectively, "Taxotere") caused them physical harms—specifically, permanent or persisting baldness, or alopecia. By agreement of the parties, the Master Long Form Complaint, and Demand for Jury Trial ("Master Complaint")[1] serves the administrative purpose of identifying the common factual allegations upon which all Plaintiffs in these consolidated actions may base their claims, and sets forth the various causes of action to which those facts would give rise under various states' laws. The resulting causes of action, which largely arise from Defendants' omission, concealment, and active misrepresentations regarding Taxotere's side effects and efficacy are: (I) Strict Products Liability – Failure to Warn; (II) Strict Products Liability – Misrepresentation; (III) Negligence; (IV) Negligent Misrepresentation; (V) Fraudulent Misrepresentation; (VI) Fraudulent Concealment; (VII) Fraud and Deceit; and (VIII) Breach of Express Warranty (against the Sanofi

[1] Rec. Doc. 312, as amended by Rec. Doc. 689 (First Amended Master Long Form Complaint and Demand for Jury Trial). To avoid any confusion, and because Defendants' memorandum in support of their motion to dismiss references paragraph numbers in Rec. Doc. 312, Plaintiffs do so as well in this memorandum in opposition.

entities only).

Defendants' Motion to Dismiss under Federal Rules of Civil Procedure 12(b)(6) and 9(b) argues not only that each of these eight causes of action is insufficiently pleaded, but also that the Master Complaint is deficient as a whole. These arguments, however, proceed not on the allegations contained in the Master Complaint but rather on Defendants' mischaracterizations and selective representations of them. Defendants' positions are altogether divorced from Plaintiffs' actual pleadings, which, as Plaintiffs illustrate below, more than sufficiently meets the standards of Federal Rules 8 and 9, for non-fraud and fraud-based claims, respectively.

Further, Defendants ignore the administrative function of the Master Complaint and instead raise arguments based on the laws of cherry-picked jurisdictions. This is wholly inappropriate, as the question for the Court at this time is whether the Master Complaint sets forth causes of action under *any* state's law, not under *every* state's law.[2] Any arguments to the contrary undermine the very purpose of the Master Complaint, and the Court should reject them, reserving such individualized, jurisdiction-specific inquiries until consideration of individual cases, either in representative trials or upon remand. Accordingly, Defendants' arguments are without merit and their Motion to Dismiss should be denied.

[2] Indeed, the exemplar Short Form Complaint (*see* PTO No. 37) provides Plaintiffs with the opportunity to supplement the allegations of the Master Complaint, as necessary to allege specific state law causes of action applicable to their individual claims.

II. THE MASTER COMPLAINT'S ALLEGATIONS OF FACT

In order to assist in the Court's orderly assessment of the allegations at issue in Defendants' Motion, Plaintiffs herein devote part of their briefing to a narrative summary of the Master Complaint's contents.

A. Allegations of Causation

Plaintiffs' allegations that Defendants' Taxotere products caused their physical injuries begin in the very first paragraph of the Master Complaint's Introduction. (Compl. ¶ 4, Doc. 312.) There, Plaintiffs allege, for the first of many times, that Taxotere can and does cause permanent hair loss, which Plaintiffs point out is a "devastating," "common," and "now well-documented side effect that for years has been publicized in numerous scientific studies, articles, and presentations." (*Id.*; *see also id.* at ¶ 5 ("Plaintiffs are women who were diagnosed with breast cancer, underwent chemotherapy using Taxotere [...], and now suffer from permanent hair loss, a side effect for which they were not warned and were wholly unprepared.").) In addition, the Master Complaint describes numerous studies, papers, and articles illustrating the causative link between use of Taxotere and the permanent alopecia alleged therein. (*Id.* at ¶¶ 149-162, 183-187.)

Aside from allegations that Taxotere can and did cause physical injuries in Plaintiffs, the Master Complaint sets forth allegations that Defendants' negligence, failures to warn, misrepresentations, concealments, and frauds were the but-for causes of those injuries. Specifically, Plaintiffs allege that, had their health care providers known that permanent hair loss could result from Taxotere use, those providers would have selected a different treatment option—one of the "effective alternatives to these drugs that do not lead to this devastating side effect [...]" (*Id.* at ¶ 5; *see also id.* at ¶ 230.) Further, each of the Master Complaint's eight counts maintain

that the pleaded acts and/or omissions caused Plaintiffs to be treated with Taxotere and suffer injuries. (*See id.* at ¶¶ 231, 239, 247, 258, 266, 276.)

B. Allegations Specific to Each Defendant[3]

Plaintiffs have alleged with specificity the labeling deficiencies at issue for each Defendant named in the Master Complaint—the Sanofi Defendants as well as the eleven 505(b)(2) Defendants who manufactured, developed, formulated, sponsored, and/or marketed Taxotere products. The Master Complaint offers for each Defendant a timeline illustrating its failures to warn of and concealment of the risk of permanent alopecia. (*See id.* at ¶¶ 46-50 (Sandoz Inc.); ¶¶ 60-63 (Accord Healthcare, Inc. and McKesson Corporation); ¶¶ 72-74 (Hospira, Inc. and Hospira Worldwide, LLC); ¶¶ 84-86 (Sun Pharma Global FZE and Sun Pharma Pharmaceutical Industries, Inc.); ¶¶ 94-97 (Pfizer Inc.); ¶¶ 106-108 (Actavis LLC and Actavis Pharma Inc.); ¶¶ 124-138 (Sanofi entities).) For example, the Master Complaint alleges the dates that Defendant Sandoz Inc. filed its New Drug Application (NDA) #201525 for its drug Docetaxel Injection on September 16, 2010, which was approved by the FDA on June 29, 2011. (*Id.* at ¶¶ 43, 45.) Plaintiffs then allege the relevant contents of Docetaxel Injection's labeling at the time it was first marketed and the date of each supplemental New Drug Application (sNDA) by Sandoz to update the drug's label. (*Id.* at ¶¶ 46-48.) The Master Complaint thereafter alleges the current label's contents, as well as its alleged deficiencies. (*See id.* at ¶¶ 49-50.) Details as to each of the other Defendants' NDA and

[3] In Rec. Doc. 689 (First Amended Master Long Form Complaint and Demand for Jury Trial), the parties agreed to amend the Master Complaint (Rec. Doc. 312) to correctly name certain Defendants. Here, Plaintiffs use the naming conventions used in the First Amended Master Complaint, because it has no impact on the issues before the Court.

sNDAs are then pleaded in turn. (*See id.* at ¶¶ 60-63; ¶¶ 72-74; ¶¶ 84-86; ¶¶ 94-97; ¶¶ 106-108; ¶¶ 124-138.)

C. Allegations Relating to Defendants' Knowledge of Taxotere Risks

The Master Complaint, at Sections III and IV, sets forth allegations of substantial and specific scientific reporting, which Defendants knew or should have known in light of its pervasiveness in the channels Defendants are tasked with monitoring. This notice began with the 1998 Sanofi-sponsored trial GEICAM 9805, which revealed that 9 percent of high-risk breast cancer patients administered Taxotere suffered hair loss for up to 10 years. (*See id.* at ¶¶ 149, 183.) The Master Complaint also pleads details of the several studies conducted and published since 2006 supporting Taxotere's link to permanent hair loss, (*see, e.g.*, ¶¶ 150, 158-162, 184, 186), and case reports published since 2009 highlighting instances of the same (*see, e.g.*, ¶¶ 152, 157, 185). It further alleges Defendants' knowledge through the following: journalistic articles and reports by *The Globe and Mail* and CBS News on permanent alopecia following Taxotere use (*id.* at ¶¶ 153-156); Sanofi's 2008 response to an inquiry from a Taxotere patient wherein the drugmaker acknowledged "non-reversible" and "ongoing" alopecia references in papers published in two medical journals (*id.* at ¶ 151); and foreign Taxotere labels and safety databases that contain warnings of the same or similar side effects at issue in this litigation (*id.* at ¶¶ 164, 167-169, 189.) These factual allegations, when viewed in the light most favorable to Plaintiffs, establish that Taxotere's propensity for causing permanent alopecia was known or knowable by all Defendants, and not just the Sanofi entities.

D. Allegations Relating to Sales and Marketing

In Section V, the Master Complaint highlights instances of Sanofi's misrepresentations, beyond those appearing in Taxotere's label, to consumers, physicians, and the general public.

Plaintiffs recount the substantial direct-to-consumer marketing push Sanofi made with its "Connection Card" gift packages beginning as early as 2000. (*See id.* at ¶¶ 192-195.) Plaintiffs also allege specific instances in 2002 where Sanofi, through its U.S. sales force, promoted Taxotere to physicians for off-label, unapproved indications (*e.g.*, "for first-line treatment of locally advanced or metastatic breast cancer"), using unsupported efficacy claims and underemphasizing the drug's risks. (*See id.* at ¶¶ 196-202.) Moreover, the Master Complaint identifies at least three 2003 direct-to-consumer magazine advertisements with efficacy misrepresentations that caused the FDA to take further action against Sanofi. (*Id.* at ¶¶ 203-207.) Plaintiffs allege that Sanofi directed its Taxotere sales force to downplay inconclusive clinical trial results, emphasize the results of weaker trials, and distort the actual safety profile of the drug (including lethal side effects) as compared to Taxol. (*Id.* at ¶ 208.) This was done to falsely promote the "superior efficacy" of Taxotere over Taxol to prescribers and consumers from 2007 until after the FDA directed Sanofi to stop in 2009. (*Id.* at ¶¶ 208-213.)

III. LEGAL STANDARD

A. Rules 8(a)(2) and 9(b), Generally

Under Federal Rule of Civil Procedure 8(a)(2), a plaintiff need only provide "'a short and plain statement of the claim showing that the pleader is entitled to relief,' in order to 'give the defendant fair notice of what the ... claim is and the grounds upon which it rests.'" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)); *see also Erickson v. Pardus*, 551 U.S. 89, 93 (2009). Accordingly, under Rule 8's general notice-pleading regime, a plaintiff need not provide detailed factual allegations. *Twombly*, 550 U.S. at 555; *see also Erickson*, 551 U.S. at 93 ("Specific facts are not necessary [...]"). When evaluating the sufficiency of a complaint, the court reads its allegations in the way most favorable to plaintiff,

accepting well-pleaded allegations as true and drawing inferences in favor of the plaintiff. *Campbell v. Wells Fargo Bank, N.A.*, 781 F.2d 440, 442 (5th Cir. 1986).

Nothing in the Supreme Court's recent pleadings jurisprudence casts doubt on these general principles. *See Swanson v. Citibank, N.A.*, 614 F.3d 400, 404 (7th Cir. 2010) ("Critically, in none of the three recent decisions—*Twombly*, *Erickson*, or *Iqbal*—did the Court cast any doubt on the validity of Rule 8 of the Federal Rules of Civil Procedure."); *Brooks v. Ross*, 578 F.3d 574, 581 (7th Cir. 2009). "While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations." *Iqbal*, 556 U.S. at 679. However, "[s]pecific facts are not necessary," *Erickson*, 551 U.S. at 93; the "[f]actual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all of the complaint's allegations are true (even if doubtful in fact)," *Twombly*, 550 U.S. at 555 (citations omitted). The Supreme Court has been careful to note, however, that the "plausibility" requirement "does not impose a probability requirement at the pleading stage; it simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence" supporting the plaintiff's legal claims. *Id.* at 556; *see also Iqbal*, 556 U.S. at 678 ("The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that defendant has acted unlawfully.").

Regarding claims of fraud, although Rule 9 requires a heightened pleading standard, Rule 9 "must not be read to abrogate Rule 8," and a court in "considering a motion to dismiss for failure to plead fraud with particularity should always be careful to harmonize the directives of Rule 9(b) with the broader policy of notice pleading." *Friedlander v. Nims*, 755 F.2d 810, 813 n.3 (11th Cir. 2001). Because the Master Complaint provides Defendants with sufficient notice of the claims asserted by Plaintiffs in this straightforward products liability action, Defendants have adequate information about all claims to enable them to answer Plaintiffs' Master Complaint.

B. Special Concerns for MDLs

In light of the administrative purpose served by master complaints, several MDL courts have refused to entertain motions to dismiss master complaints where doing so would require case-specific rulings to determine the sufficiency of each individual plaintiff's factual allegations. *See In re Zimmer Nexgen Knee Implant Prods. Liab. Litig.*, 2012 WL 3582708 (N.D. Ill. 2012); *In re Nuvaring Prods. Liab. Litig.*, 2009 WL 4825170, at *2 (E.D. Mo. Dec. 11, 2009); *In re Trasylol Prods. Liab. Litig.*, 2009 WL 577726, at *8 (S.D. Fla. Mar. 5, 2009). For example, faced with over 400 separate cases, the *Trasylol* court assessed the sufficiency of the master complaint's fraud claims with "substantial leniency," concluding that the specificity demanded by defendant would "completely remov[e] the compromise and attempt at efficiency the Parties and [the court] had in mind in allowing the filing of the Consolidated Master Complaint." *Id.* at *8. Similarly, the *Nuvaring* court concluded that case-specific rulings on the sufficiency of the plaintiffs' allegations "are neither the purpose, nor the forte of a court presiding over a multi-district litigation." *Nuvaring*, 2009 WL 4825170, at *2 (quoting *In re Phenypropanolamine Prods. Liab. Litig*., 2004 WL 2034587, at *2 (W.D. Wash. Sept. 3, 2004)). Rather, "[a] MDL seeks to promote judicial economy and litigant efficiency by allowing the transferee court to preside over matters common among all cases [...] Given this function, the transferee court typically does not rule on cumbersome, case-specific legal issues." *Id.* Instead, the proper court to hear dispositive motions concerning the sufficiency of plaintiff-specific allegations is the transferor court, Manual for Complex Litigation (Fourth) § 22.37 ("When the MDL pretrial proceedings are concluded and individual cases are remanded to the transferor courts, the transferor judge must decide whether additional discovery and other pretrial work require completion, including deciding dispositive

motions"), or this Court when it considers Short Form Complaints in exemplar cases.

IV. ARGUMENT

A. The Master Complaint Is Not a "Shotgun Pleading" in Violation of Rule 8's Pleading Standards.

Defendants complain that each count of the Master Complaint incorporates by reference "long narrative sections" of the Master Complaint, "making it virtually impossible for Defendants to identify which facts are part of which cause of action." (Defs. Mem. Doc. 489-1 at 5.) They assert that these pleadings place an unreasonable burden on them in responding to the allegations of the Master Complaint and on this Court in interpreting the pleadings. Moreover, Defendants urge that through the assertion of seven of eight causes of action against "all Defendants," they and this Court cannot determine which Defendants have engaged in which acts, thereby providing them with inadequate notice of the grounds for the claims against each Defendant.

Defendants' contentions echo those made by the defendants in *Trasylol*, 2009 WL 577726, at *5. There, plaintiffs incorporated by reference all general allegations contained in the preceding paragraphs of the complaint in each count and, according to defendants, the counts were therefore deficient because these "shotgun pleadings" only "vaguely allege[d] that 'Defendants'—without specifying which defendant, when or to whom the statement was directed—made unspecified 'innocent, negligent and/or willful misrepresentations regarding the safety, efficacy, and risk benefit ration [sic] of Trasylol … [and] concealed material facts from physicians and consumers … concerning the character and safety of Trasylol in their 'advertising, promoting and otherwise.'" *Id.* Finding that the complaint was not a shotgun pleading and was sufficient to adequately put the defendants on notice of the claims against them, the MDL court distinguished between shotgun pleadings "where a party throws every fact into every claim and hopes that something sticks," and pleadings which contain "mere surplusage," *i.e.*, factual allegations that are incorporated into a

particular count but do not necessarily add anything to the claim. *Id.* at *6 (citing *Bailey v. Janssen Pharmaceutica, Inc*., 2008 WL 2898214 (11th Cir. 2008)).

Likewise, in *In re Zimmer*, 2012 WL 3582708, the court, after surveying MDLs throughout the country that implemented the filing of master complaints, noted that "[w]ith more than 549 individual actions already consolidated in this litigation, the Master Complaint cannot be expected to include specific factual matter for claims that require plaintiff-specific proof." *Id.* at *4 (citing Manual for Complex Litigation (Fourth) §22.37). Recognizing the "substantial leniency" afforded the allegations of the master complaint in *Trasylol*, the court found that, in general, the allegations of the complaint "give Defendants sufficient notice of the nature of the [design] defect Plaintiffs allege [and] support a reasonable inference that the product failed to perform as an ordinary consumer would expect…" *Id.* at *9. The court also reached similar conclusions with regard to plaintiffs' failure to warn, negligent misrepresentation, express warranty, implied warranty and fraud claims and declined to dismiss those claims. *Id*. at *10-12.

Here, considering that this MDL is comprised of claims from nearly all of the 50 states, Plaintiffs cannot be expected to plead the laws of all jurisdictions, the specific misconduct of each Defendant and the misrepresentations any single Defendant made to any particular Plaintiff or healthcare provider. Defendants have been provided with more than adequate notice of the claims asserted by Plaintiffs to allow Defendants to plead to these claims, and any surplusage in the Master Complaint, assuming there is any, does not render it an improper "shotgun pleading."

B. Plaintiffs Have Adequately Pleaded Causation.

Similarly, Defendants complain that the Master Complaint fails to include specific allegations of causation, such as, *inter alia*, failing to allege that "docetaxel caused their alleged permanent hair loss…that absent their use of docetaxel, they would not have experienced

permanent hair loss… [and] had the labeling said something different about alopecia, Plaintiffs' prescribing physicians would have made a different prescribing decision." (Defs.' Mem. , Doc. 489-1 at 7-8.) Setting aside that Defendants have overstated the necessary elements of a products liability action throughout their causation arguments, such a challenge is not appropriate with respect to a master complaint. With hundreds of actions consolidated in this MDL proceeding, "the Master Complaint cannot be expected to include specific factual matter for claims that require plaintiff-specific proof." *In re Zimmer,* 2012 WL 3582708, at *4.

Plaintiffs' allegations of causation are more than adequate in light of the purpose of the Master Complaint. Moreover, and contrary to Defendants' contention, Plaintiffs have included express allegations that Defendants' conduct caused their injuries. Plaintiffs allege:

> ¶4[Defendants] have known for years that these drugs cause permanent hair loss, a now well-documented side effect that for years has been publicized in numerous scientific studies, articles, and presentations. Despite this, these brand-name entities failed to warn patients and healthcare providers of the risk of permanent hair loss and report this risk to the Food and Drug Administration ("FDA"). Instead, Defendants hid this devastating side effect. In fact, some brand-name entities still fail to disclose that permanent hair loss is a common side effect.
>
> ¶5 Plaintiffs are women who were diagnosed with breast cancer, underwent chemotherapy using Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate and/or Docefrez, and now suffer from permanent hair loss, a side effect for which they were not given warned and were wholly unprepared. Had Plaintiff and Plaintiffs' healthcare providers known that permanent hair loss could result, they would have selected a different treatment option – effective alternatives to these drugs that do not lead to this devastating side effect are used regularly.
>
> ¶6-7 As a result of this undisclosed side effect, Plaintiffs have struggled to return to normalcy, even after surviving cancer […] Defendants failed, and some still fail, to warn that permanent or irreversible hair loss is a common side effect of Taxotere [...] and Plaintiffs have been unable to weigh this devastating possibility when deciding among treatment options.
>
> ¶8 Plaintiffs in these individual actions have suffered personal injuries as a result of the use of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate and Docefrez.

> ¶9 Plaintiffs have suffered personal injuries as a direct and proximate result of Defendants' conduct and misconduct as described herein […]
>
> ¶230 Plaintiffs would not have used Taxotere, Docefrez, Docetaxel Injection and Docetaxel Injection Concentrate had they (and their physicians) been provided an adequate warning by Defendants of the risks of these side effects [permanent alopecia].
>
> ¶231 As a direct and proximate result of Defendants' failure to warn of the potentially severe adverse effects [permanent alopecia] of Taxotere [etc.], Plaintiffs suffered and continue to suffer serious and dangerous side effects […] including permanent alopecia […]

These specific allegations of causation are more than sufficient to meet Plaintiffs' burden under Rule 8 to adequately allege causation, where individualized allegations are not possible in a Master Complaint. Plaintiffs' allegations directly address, either implicitly or explicitly, all of the pleadings deficiencies advanced by Defendants. This includes that: Taxotere causes permanent hair loss (Compl. ¶ 4, Doc. 312); absent use of Taxotere Plaintiffs would not have experienced permanent hair loss (*id.* at ¶ 5); another drug would have successfully treated Plaintiffs' cancer (*id.* at ¶ 5); Plaintiffs' physicians read the label (*id.* at ¶ 230); and, had the labeling adequately warned about alopecia, Plaintiffs' prescribing physicians would have altered their prescribing decisions (*id.* at ¶¶ 6-7).[4] More specific allegations of causation could not, as a practical matter, be included in the Master Complaint. As the *Trasylol* court noted, it would be impossible to satisfy Defendants' demands of specificity "without completely removing the compromise and attempt at efficiency" sought by the Master Complaint procedure. *Trasylol*, 2009 WL 577726, at *8.

[4] The "heeding presumption," applicable under the laws of some states, including Louisiana, assumes that if an adequate warning had been provided, the plaintiff's physician would have followed that warning and the plaintiff would not have been injured. *In re Xarelto (Rivaroxaban) Prod. Liab. Litig.*, No. 2592, 2017 WL 1393480, at *3 (E.D. La. Apr. 17, 2017) (citing *Bloxom v. Bloxom*, 512 So.2d 839, 850 (La. 1987)).

C. Plaintiffs Have Sufficiently Alleged a Strict Products Liability Claim for Misrepresentation.

The second claim for relief in the Master Complaint asserts a cause of action for strict products liability for misrepresentation—a theory of recovery found in § 402B of the Restatement (Second) of Torts. Defendants assert this claim should be dismissed because (1) not all states recognize a § 402B cause of action; (2) Plaintiffs have not pleaded any express misrepresentations; and (3) Plaintiffs' allegations lack specificity. As detailed below, none of these arguments have merit.

1. Universal availability of Restatement §402B liability is not a pleading requirement for Plaintiffs' Master Complaint.

Defendants contend that not all states recognize a §402B cause of action for strict products liability for misrepresentation. This is irrelevant in the context of the Master Complaint. As noted above, the Master Complaint serves the administrative purpose of identifying the factual allegations upon which Plaintiffs may base their claims. The Master Complaint is *not* intended to include causes of action applicable to all Plaintiffs but is drafted "in the broadest sense, pursuant to all applicable laws and pursuant to choice of law principles, including the law of each Plaintiff's home state." (Compl. ¶ 2; Doc. 312.) Indeed, the Master Complaint specifically anticipates this, providing that "individual Plaintiffs will adopt this Master Complaint and selected causes of action herein through the use of a separate Short Form Complaint." (*Id.* at ¶ 3.) Thus, the unavailability of a strict products liability claim for misrepresentation in all jurisdictions provides no basis for dismissal of this cause of action.

2. Plaintiffs have sufficiently alleged express misrepresentations to state a claim for strict products liability under Rule 8.

Defendants assert that Plaintiffs have failed to allege *any* express misrepresentation, only "representations inferred from the nondisclosure of facts." (Defs.' Mem., Doc. 489-1 at 12.) The

allegations contained in the Master Complaint belie this assertion. For instance, Plaintiffs have clearly conveyed that Defendants did not merely omit warnings about the known risk of permanent alopecia, but repeatedly positioned Taxotere as a safe and effective treatment that had greater efficacy and survival outcome than its competitors. (Compl. ¶¶ 191-213, Doc. 312.) Plaintiffs have alleged that "Sanofi directed its U.S. sales force to misrepresent the safety and effectiveness of the off-label use of Taxotere to expand the market for Taxotere in unapproved settings, such as a first-line of treatment or for early-stage breast cancer." (*Id.* at ¶ 197.) In addition, Plaintiffs allege a series of advertisements, each of which was censured by the FDA; Plaintiffs have specified the publications or other media in which each misleading message appeared. (*See id.* at ¶¶201-206.) Plaintiffs have adequately pleaded that Defendants' misrepresentations were specific, explicit, and intended to induce Plaintiffs to consume Taxotere.

3. Plaintiffs' allegations of Defendants' misrepresentations are sufficiently particular to meet Rule 9(b) standards, even though they need only comply with Rule 8.

Defendants' argument that allegations sounding in strict products liability for misrepresentation require heightened particularity runs contrary to the language of Rule 9(b), which by its terms applies only to allegations of fraud (or mistake). The plain language of the Restatement demonstrates that fraud is not an element of a § 402B cause of action:

> One engaged in the business of selling chattels who, by advertising, labels, or otherwise, makes to the public a misrepresentation of a material fact concerning the character or quality of a chattel sold by him is subject to liability for physical harm to a consumer of the chattel caused by justifiable reliance upon the misrepresentation, *even though . . . it is not made fraudulently* or negligently.

Restatement (Second) of Torts § 402B (1965) (emphasis supplied); (*See also* Defs.' Mem., Doc. 489-1 at 11.)

Defendants nonetheless claim that *America Realty Trust, Inc. v. Travelers Casualty &*

Surety Company of America, 362 F. Supp. 2d 744 (N.D. Tex. 2005), supports the application of Rule 9(b) to Plaintiffs' misrepresentation claims. Not so. Unlike Plaintiffs' Master Complaint, the complaint in *American Realty*, originally filed in state court, included a single hybrid count labeled "fraud and negligent representation." Upon removal to federal court, the plaintiff acknowledged that the fraud allegations had not been pleaded in accordance with Rule 9(b)'s particularity requirements. *Id.* at 748. Rather than attempt to untangle the factual basis for the "fraud" claim from the "negligent" representation claim, the court dismissed the entirety of the allegations without prejudice, but noting specifically that "the text of Rule 9(b) precludes any interpretation that would require a plaintiff to plead negligent misrepresentation, per se, in conformity with the heightened requirements." *Id.* at 749 ("Rule 9(b) has no application to circumstances that do not constitute fraud or mistake, such as nonfraudulent misrepresentation.").

Even if Plaintiffs are under a burden to allege fraudulent conduct with the particularity required by Rule 9(b), Plaintiffs' Master Complaint is more than sufficient. As explained *infra* in Section E, Defendants are more than adequately apprised of the specific conduct (the "who, what, when, where, and how") of which Plaintiffs complain, and cannot reasonably suggest that the Master Complaint has left them unable to prepare a master answer.

D. Plaintiffs Have Adequately Pleaded Breach of Express Warranty Against the Sanofi Defendants.

In their eighth claim for relief, Plaintiffs assert a breach of express warranty claim limited to the Sanofi-related entities. The Sanofi Defendants contend principally that Plaintiffs have failed to identify any information that was "expressly warranted" to Plaintiffs or their prescribing physicians, and that Plaintiffs have pleaded only omissions of warnings they allege should have been included.

Regarding the Sanofi Defendants' claim that Plaintiffs have not pleaded an express warranty, Plaintiffs allege in Paragraph 313 of the Master Complaint that:

> Defendants expressly warranted to Plaintiffs and Plaintiffs' healthcare providers that Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate were safe and fit for the use for the purposes intended, that they did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for cancer, that the side effects they did produce were accurately reflected in the warnings, and that they were adequately tested.

(Compl. ¶ 313, Doc. 312.) Similar allegations have been found sufficient by other courts. For example, in *Young v. Bristol-Meyers Squibb Co.*, 2017 WL 706320, at *14-15 (N.D. Miss. Feb. 22, 2017), nearly identical allegations pertaining to the drug Farxiga were found to have been alleged with enough specificity to survive the defendants' motion to dismiss. In reaching this conclusion, the court recognized that a claim for breach of express warranty is not subject to the heightened pleading standards of Rule 9(b) and that under Rule 8's relaxed pleading standards numerous "courts have found similar allegations to be sufficient to state a claim for express warranty." *Id.* at *15; *see also Rayford v. Karl Storz Endoscopy Am., Inc.*, 2016 WL 4398513 (W.D. La. June 22, 2016) (finding under Louisiana law the express warranty by defendants that "their product was safe and effective for the procedure" plaintiff underwent was sufficient to support a breach of express warranty claim); *Ivory v. Pfizer, Inc.*, 2009 WL 3230611, at *5 (W.D. La. Sept. 30, 2009) (finding that the allegations of the complaint concerning breach of express warranty were more than enough at the pleading stage under *Twombly* "to raise a right to relief above the speculative level"); *Harris v. Merck & Co., Inc.*, 2012 WL 1970882, at *3 (W.D. La. Nov. 1, 2012) (finding that plaintiff's complaint adequately provided notice of his express warranty claim despite his failure to "point to the specific warranty language it alleges was violated").

Next, the Sanofi Defendants complain of Plaintiffs' failure to identify how Plaintiffs or their prescribing physicians supposedly relied on any express warranty. As the MDL Court remarked in *In Re Zimmer*, 2012 WL 3582708, at *12, "this court cannot envision a Master Complaint pleaded with the type of plaintiff-specific particularity Defendants believe is necessary." Plaintiffs have stated in paragraph 315 of the Master Complaint that they and their healthcare providers relied on Defendants' express warranties in electing to "purchase and use their product," and under the relaxed pleading standards of Rule 8, as well as the substantial leniency with which a plaintiff-specific claim should be viewed at this stage of the litigation, Plaintiffs have adequately pleaded reliance upon Defendants' express warranties. (Compl. ¶315, Doc. 312.)

Lastly, the Sanofi Defendants claim they cannot be held liable for how any product, other than their own, was allegedly warranted and cite *Johnson v. Teva Pharmaceuticals U.S.A. Inc*., 758 F. 3d 605, 616 (5th Cir. 2014), in support of this proposition. While *Johnson* was decided under Louisiana law and found that a brand-name drug manufacturer could not be held liable for injuries caused by ingestion of a generic drug, the law on this so-called "innovator liability" is not nearly as settled under the laws of other states. For example, in *McNair v. Johnson & Johnson*, 2017 WL 2333843 (4th Cir. May 30, 2017), the Fourth Circuit recently certified to the Supreme Court of Appeals of West Virginia the question "[w]hether West Virginia law permits a claim of failure to warn and negligent misrepresentation against a branded drug manufacturer when the drug ingested was produced by a generic manufacturer." *Id.* at *1. The court found that under California, Vermont, and Alabama law the brand-name manufacturers could be held liable for harm caused by a generic drug, whereas the laws of Louisiana, Oklahoma, Florida, Tennessee, and Arkansas would prohibit the imposition of liability. *Id.* at *4. Because it is beyond dispute that in

certain jurisdictions innovator liability is actionable, this is not a basis for the Sanofi Defendants to seek dismissal of the express warranty claim in the Master Complaint.

E. Plaintiffs' Misrepresentation and Negligent Misrepresentation Claims Are Sufficiently Pleaded under Rule 8, and Plaintiffs' Fraud-Based Claims Meet the Heightened Requirements of Rule 9.

1. Rule 9(b) does not apply to the Master Complaint's negligent misrepresentation and strict liability misrepresentation causes of action, which are not premised on allegations of fraud.

Defendants assert that Rule 9(b) applies to Plaintiffs' misrepresentation (discussed *supra* at Part C(3)) and negligent misrepresentation claims because those claims are premised on Defendants' "false and misleading statements and omissions." This is an incorrect statement of law unsupported by the cases Defendants cite, including *Benchmark Electronics, Inc. v. J.M. Huber Corp.*, 343 F.3d 719, 723 (5th Cir. 2003), and *Lone Star Ladies Investment Club v. Schlotzsky's Inc.*, 238 F.3d 363, 368 (5th Cir. 2001). In fact, the district court's opinion in *American Realty* (which Defendants themselves cite) has explicitly rejected Defendants' argument—*i.e.*, that misrepresentation or negligent misrepresentation claims "become subject to heightened pleading simply because they are based on the same set of operative facts as corresponding fraud claims." 362 F. Supp. 2d at 749. Under a proper reading of the jurisprudence on Rule 9(b), it is not the *causes of action* that are subject to heightened pleading standards, but rather any component, fraud-based averments of fact that are pleaded in support of those causes of action.[5]

[5] "As an initial matter, the text of Rule 9(b) precludes any interpretation that would require a plaintiff to plead negligent misrepresentation, per se, in conformity with the heightened requirements." *Id.* at 749. "This means that Rule 9(b) has no application to circumstances that do not constitute fraud or mistake, such as nonfraudulent misrepresentation." *Id.* (citing *Benchmark Elec., Inc.*, 343 F.3d at 723 ("Rule 9(b) by its terms does not apply to negligent misrepresentation claims.")).

The only circumstances where Rule 9(b) might apply to and warrant dismissal of a claim for which fraud is not in fact an element is where that claim is nonetheless based upon inadequately specific averments of fraud. *Id.* at 750 (citing *Melder v. Morris*, 27 F.3d 1097, 1100 (5th Cir. 1994)). In other words, dismissal is only required where an "inadequate fraud claim is so intertwined with the negligent misrepresentation claim that it is not possible to describe a simple redaction that removes the fraud claim while leaving behind a viable misrepresentation claim." *Id.* ("One must first disregard inadequate averments of fraud. At that point, Rule 9(b) is no longer relevant. The remaining question is whether a negligent misrepresentation claim is stated under the standard notice pleading principles applicable to such claims.")

The Master Complaint's negligent misrepresentation and strict-liability misrepresentation causes of actions are well pleaded independently from any allegations of fraud that may appear incidentally therein. First, with regard to the negligent misrepresentation claim, even if allegations that might arguably touch on fraudulent and deceptive intent, willful acts, or motive are not considered (*see* Compl. ¶¶ 251-254, Doc. 312.), Plaintiffs have more than sufficiently pleaded an actionable claim under standard notice pleadings. The Master Complaint avers that "Defendants had a duty to represent to Plaintiffs [and others] that Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate had been tested and found to be safe and effective for the treatment of various forms of cancer" (*id.* at ¶ 249) and that they breached that duty (1) by "negligently represent[ing] that they had been tested and [were] found to be safe and/or effective for [their] indicated use" (*id.* at ¶ 250); (2) by failing "to exercise ordinary and reasonable care in their representations of Taxotere while involved in its manufacture, sale, testing, quality assurance, quality control, and or distribution" (*id.* at ¶ 255); (3) by negligently misrepresenting the drugs' "high risks of unreasonable, dangerous side effects" (*id.*); and (4) by "misrepresenting [the drugs']

serious side effects to Plaintiffs" and others (*id.* at ¶ 256). Plaintiffs have further pleaded reliance (*id.* at ¶ 257), causation (*id.* at ¶ 258), and damages (*id.*). In addition, with regard to Plaintiffs' strict liability misrepresentation claim, that cause of action relies on no averments of fraud whatsoever that might be subject to Rule 9(b)'s heightened pleading requirements. (*See id.* at ¶¶ 232-239, discussed in Part C, *supra*.) Accordingly, Rule 9(b) has no import for the Master Complaint's strict liability misrepresentation and negligent misrepresentation claims, which are not based on averments of fraud.[6]

2. The Master Complaint's Fraud-Based Causes of Action Comply with Rule 9(b)'s Requirements.

The Master Complaint's claims of fraudulent misrepresentation, fraudulent concealment, and fraud and deceit allege facts at length that are sufficient to meet Rule 9(b)'s standards. The Rule requires a party alleging fraud to "state with particularity the circumstance constituting fraud," except for "[m]alice, intent, knowledge, and other conditions of a person's mind," which "may be alleged generally." Fed. R. Civ. P. 9(b). "Rule 9b should be applied with a view to its purposes which are (1) to inform the defendants of the claimed wrong and enable them to formulate an effective response; and (2) to protect defendants from unfounded, conclusory charges of fraud." *Carl v. Galuska*, 785 F. Supp. 1283, 1287 (N.D. Ill. 1992); *see also Sec. & Exch. Comm'n v. Blackburn*, 156 F. Supp. 3d 778 (E.D. La. 2015) (quoting *Tuchman v. DSC Commc'ns Corp.* 14 F. 3d 1061, 1067 (5th Cir. 1994)) (The heightened pleading standard of Rule 9(b) is meant to "provide[] defendants with fair notice of the plaintiffs' claims [and]…prevent[] plaintiffs from filing baseless claims and then attempting to discover unknown wrongs").

[6] Should the Court disagree and find that these claims by Plaintiffs are dependent on or inseparable from averments of fraud, Plaintiffs respectfully direct the Court to Part E.2, which immediately follows and outlines why Plaintiffs' fraud allegations comply with Rule 9(b).

Just as with each of Defendants' other arguments, Defendants here present the Court with only a sliver of the entirety of Plaintiffs' allegations in an attempt to characterize their claims as deficient.[7] Even a cursory look at the Master Complaint, however, reveals a pleading rich in detail, especially as it pertains to averments of fraud. First, Master Complaint paragraphs 149 to 169 recite, with reference to many specific examples, allegations of Defendants' knowledge, among other things, of the propensity of their drugs to cause the injuries at issue in this MDL while concealing it from and/or failing to warn patients, health care professionals, the medical community, or the public in the U.S. (Compl. ¶¶ 149-169, Doc. 312.) Second, paragraphs 191-213 spell out nearly a decade of specific actions by Defendants to misleadingly and/or fraudulently market their drugs' relative safety and efficacy. (*Id.* at ¶¶ 191-213.) Further, each of the counts in question incorporates (*id.* at ¶¶ 259, 267, 277) and often even lays out in additional detail (*id.* at ¶¶ 270, 284-296), the averments supporting the frauds alleged. Beyond that and without the benefit of discovery, Plaintiffs should not be required to allege with more specificity facts which are exclusively within Defendants' knowledge. *See U.S. ex rel. Willard v. Humana Health Plan of Texas Inc.*, 336 F.3d 375, 385 (5th Cir. 2003) ("pleading requirements of Rule 9(b) may be to some extent relaxed where . . .the facts relating to the alleged fraud are peculiarly within the perpetrator's knowledge"); *see generally Michaels Bldg. Co. v. Ameritrust Co.*, N.A., 848 F.2d 674, 680 (6th Cir. 1988) ("Courts have held that the [Rule 9(b) particularity requirement] may be relaxed where information is only within the opposing party's knowledge. Especially in a case in which there has been no discovery, courts have been reluctant to dismiss the action where the facts underlying the claims are within the defendant's control.") (internal citations omitted).

[7] Indeed, Defendants present the Court with only four sentences from Plaintiffs' 321-paragraph Master Complaint, all of which are taken from the various counts and not the detailed, 220-paragraph fact section that precedes them.

In sum, these allegations, taken together with the scope of an MDL and the administrative purposes of a Master Complaint, more than meet the requirements of Rule 9(b), which is intended to provide notice and advance fairness, especially considering the "substantial leniency" generally afforded to Plaintiffs in complex litigations with special administrative concerns.

V. CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss should be denied. If any claim is dismissed, Plaintiffs request leave to amend. *See Jebaco Inc. v. Harrah's Operating Co. Inc.*, 587 F.3d 314, 322 (5th Cir. 2009) ("leave to amend is to be granted liberally unless the movant has acted in bad faith or with a dilatory motive, granting the motion would cause prejudice, or amendment would be futile"); *Cates v. Int'l Tel. & Tel. Corp.*, 756 F.2d 1161, 1180 (5th Cir. 1985) ("[D]eficiencies do not normally justify dismissal of the suit on the merits and without leave to amend, at least not in the absence of special circumstances.").

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on July 31, 2017, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system which will send a notice of electronic filing to all counsel of record who are CM/ECF participants.

/s/ M. Palmer Lambert
M. PALMER LAMBERT